I. AMENDMENTS

A. Amendments To The Specification

Please amend pages 12, 14, 17, 19, 25, and 29, as indicated on the marked-up pages attached hereto.

Does not enter spec changes
10-15-03

Figure 4C also shows an insert (228) having both a significant meridional length component (230) and a significant width or circumferential component (232). The ratio of the length of the meridional length component (230) to the width or circumferential component (232) in the variation shown in Figure 4C is also about 1.0.

The concept of measuring the meridional length of the inserts by observing the length of the insert which falls along a meridian (206) of the cornea should be clear from the examples shown in Figures 4A, 4B, and 4C.

Figure 5A shows a front view of an insert (216) made according to the invention. Figure 5B shows a side view of the Figure 5A insert in relation to the anterior corneal surface which follows the external epithelium (31). The side view shows a desirable embodiment in which the insert's centroidal axis follows an intracorneal arc (229) in a direction parallel to a corneal meridian, and if not pliable, exhibits a pre-shaped radius of curvature (234) before implantation, as well as after implantation. Such a device is referred to as "radially arcuate." The radius of curvature (234) approximates, *e.g.*, lies between, the hemispherical radii (213 and 215) shown in Figure 3C at the depth of implantation in the cornea into which it is placed. This radius of curvature (*i.e.*, the radius of curvature measured along the centroidal axis of the insert, or that portion of the insert intended to extend generally radially within the cornea) is preferably greater than 5 mm, more preferably greater than 5.5 mm, and typically ranges from 6 to 9 mm. In a preferred embodiment, the radius of curvature ranges from 7 to 8 mm.

Figure 5B also shows that the insert has a centroidal length ("ℓ") measured along its centroidal axis at a given radius of curvature (234). This centroidal length "ℓ" subtends an arc having an angle "δ". This value is referred to herein as the "meridional arc angle". The value of δ is preferably less than or equal to 90°, and more preferably less than or equal to 45°.

The device of Figure 5B may have a variety of different cross sectional configurations. Figure 5C, for example, shows a cross sectional view of the

well as a circumferential portion (246). Again, the side view found in Figure 7B shows an optional corneal radius of curvature such as discussed in relation to Figures 5A and 5B.

Figure 8A shows a front view of a boomerang-shaped variation (250) of the inventive insert having a radial leg (252) and a circumferential portion (254). The side view found in Figure 7B shows an optional radius of curvature. The radial leg (252) is not situated in such a way that it is placed in line with a meridian of the cornea but it can be conceptualized as being a distributed or functionally wider radial leg.

Further, the typical width of the individual inserts discussed above is often between 0.2 mm and 2.0 mm. The typical thickness is often between 0.15 mm and 0.5 mm. In addition to the width and thickness of the insert tapering at one or both ends, the thickness of the insert may optionally vary from one end to the other end of the insert (*e.g.*, along the centroidal length of the insert) to provide for a desired change in corneal curvature at the location of the insert. The centroidal length of the insert (*i.e.*, the length of the insert measured along the centroidal axis of the insert) is contemplated to rarely ~~exceeds~~ exceed 3.0 mm. Preferably, the insert has a centroidal length which is less than or equal to 2.5 mm, and more preferably less than 2.0 mm. When the centroidal length is determined for an insert configuration other than the simple configuration shown in Figure 4A (*e.g.*, such as the insert shown in Figures 4B), the centroidal length corresponds to the length of the radially arcuate portion measured along the centroidal axis of that portion. As another example (*e.g.*, the insert of Figure 4C), this length corresponds to the length of the generally radially extending leg (*e.g.*, the non-circumferentially extending portion) measured along its centroidal axis. These parameters (along with certain other variables such as the cross-sectional shape of the device and its constituent polymers and stiffness) determine, in large part, the level of correction achievable by use of a selected insert.

Other non-limiting forms for the inventive insert are exemplified in Figures 9-15. Figure 9 shows a perspective view of an insert (231) having a

which are incorporated by notice. The specific array of radial inserts (202) and circumferential segments (239) is not limited to the alternating pattern shown in the Figure, nor is the invention limited to the positioning or numbers of inserts shown in the Figure. The choice of and placement of appropriate ~~inserts~~ insert and segments is left to the attending health professional based upon the abnormality to be treated.

The materials used in these inserts may be relatively stiff (high modulus of elasticity), physiologically acceptable polymers such as acrylic polymers like polymethylmethacrylate (PMMA) and others; polyfluorocarbons such as TEFLON; polycarbonates; polysulfones; epoxies; polyesters such as polyethyleneterephthalate (PET), KODAR, and Nylon; or polyolefins such as polyethylene, polypropylene, polybutylene, and their mixtures and interpolymers. Certain glasses are also suitable for the devices. By "high modulus of elasticity" is meant a modulus greater than about 3.5 kpsi. Many of these polymers are known in the art to be appropriately used in hard contact lenses. Obviously, any polymer which is physiologically suitable for introduction into the body is useful in the inserts of this invention. Many of the listed polymers are known to be suitable as hard contact lenses. For instance, PMMA has a long history in ophthalmological usage and consequently is quite desirable for use in these inserts.

Additionally, the polymeric material making up the insert may be one or more low modulus polymers, e.g., those having a modulus of elasticity below about 3.5 kpsi, more preferably between 1 psi and 1 kpsi, and most preferably between 1 psi and 500 psi, which are physiologically compatible with the eye. Most polymeric materials used in soft contact lenses are suitable the inserts of this invention. The class includes physiologically compatible elastomers and such polymers, typically crosslinked, as polyhydroxyethylmethylacrylate (Poly-HEMA) or polyvinylpyrrolidone (PVP), polyethylene oxide, or polyacrylates, polyacrylic acid and its derivatives, their copolymers and interpolymers, and the like as well as biologic polymers such as crosslinked

a drug such as dexamethasone to reduce acute inflammatory response to implanting the device. This drug may help to prevent undesirable vascular ingrowth toward the intrastromal segment and improve the overall cosmetic effect of the eye with the insert and segment. Similarly, heparin, corticosteroids, antimitotics, antifibrotics, antiinflammatories, anti-scar-forming, anti-adhesion, and antiangiogenesis factors (such as nicotine adenine dinucleotide (NAD^+)) may be included to reduce or prevent angiogenesis and inflammation.

Clearly, there are a variety of other drugs suitable for inclusion in the intrastromal segment. The choice will depend upon the use t: which the drugs are placed.

Figure 19A is a side view of a variation of the intrastromal sector or insert (260) made of a low modulus polymer system or hydratable outer coating (262). Figure 19B shows the inner cavity (264) of the insert. This intrastromal segment may be inserted into the intrastromal space created by the dissector as a covering on a tool similar to the dissector which created the intracorneal pocket or channel. Once in position the insertion tool is rotated out of the intrastromal segment leaving the shell within the stroma.

Figure 19B shows the inner cavity (264) which may be filled with a biologic, a drug or other liquid, or biologically active eye treatment material. These devices may be tied or pinched or crimped or otherwise closed, typically at their point of insertion, by known techniques. If the inserts were closed or sealed prior to introduction, the insert may later be punctured with a syringe and a fluid or gel ~~may be~~ may introduced or withdrawn for a variety of clinical reasons.

The shell (262) may be injected with a settable soft polymer core (264), allowed to expand to a desired thickness, and set. Polymeric gels which do not polymerize in situ are preferred. Suitable injectable polymers are well known but include polyHEMA hydrogel, cross-linked collagen, cross-linked hyaluronic acid, PVP, polyacrylonitriles, polyacrylamides, polyacrylic acids, their copolymers and terpolymers, vinyl alcohol derivatives, etc. Siloxane gels and organic-siloxane

in Figure 36A. The obtuse angle provides the user with a comfortable handle position when tip 156 is inserted into the incision. Tip 156 has a tapering thickness t which decreases in the direction from the extension 154 to tip end 158.

As shown in Figure 36B, tip end 158 is rounded and is preferably substantially hemispherical. although greater and lesser radii of curvature may be employed to define the tip end. Importantly, the tip end is not knife sharp, but rather, is relatively blunt so as to function to separate tissue along layers, but not to cut.. Tip end 158 transitions into tip sides 160 as the curvature of tip end 158 gradually straightens into the substantially straight edges of tip sides 160. Tip sides 160 are sharp, although not knife sharp. A comparison of the relatively dull edge of tip end 158 and the relatively sharp edges of tip sides 160 can be seen by comparing the sectional views of Figures 36C and 36D, respectively.

With the arrangement of stromal spreader tip 156 as described, the relatively dull, slightly rounded tip end 158 greatly reduces the risk of perforation of the corneal tissues upon insertion of the tip into the incision. Additionally, by rotating the spreader using handle 152 the stromal layers ~~are~~ can be effectively separated to form a pocket, or enlarge or otherwise modify an initial pocket created by the corneal pocketing tool described above.

Figure 36E illustrates, in an exaggerated way, the transition between blunt tip end 158 and the relatively sharp edge of tip side 160, which supports the fact that the insertion of the tip presents a relatively low risk of perforation of the stromal tissues. Once the spreader has been inserted, separation can begin through use of sharper side edges 160, together with blunt tip end 158.

Figure 36F shows a variation of the tip shown in Figure 36A. In this variation, the joinder of tip 156 and extension 154 is formed at the obtuse angle β to the longitudinal axis of extension 154 and handle 152, the same as shown in Figure 36A. However, the majority of the tip that is distal to the joinder of the tip and the extension, i.e., tip 156' is formed at an angle γ with regard to the longitudinal axis of extension 154 and handle 152, and where angle γ is an obtuse angle that is less than obtuse angle β. The remaining features of tip 156' are

The number of inserts and the size and shape of each circumferential insert and radial insert are determined by the amount of reshaping of the cornea that is needed to provide a spherically-shaped cornea in the patient's eye.

Turning now to the specifics of the instruments discussed above, the corneal marker used to make the marks on the cornea to guide subsequent surgical procedures may be constructed in a number of ways. A corneal marker may be provided which has an incision marker, clockwise and counterclockwise channel markers, and radial pocket markers which form their corresponding marks simultaneously when the corneal marker is pressed against the patient's eye.

Alternatively, multiple corneal markers can be used to form the incision mark, the clockwise and counterclockwise circumferential channel marks, and the radial pocket marks which aid the surgeon during surgery. For example, two corneal markers can be used to form the desired marks. One corneal marker may have an incision marker, clockwise and counterclockwise channel markers, and a reticule or sight to enable the corneal marker to be aligned to the center mark (360) of the patient's cornea. The second marker may have radial pocket markers and a reticle or sight. Each corneal marker is individually aligned with the center mark (360) and pressed against the patient's cornea to form the desired marks. The combined incision/circumferential channel markers is usually pressed against the cornea before any vacuum centering guide is placed thereon so that the surgeon can easily make the initial incission into the cornea. After the vacuum guide is centering guide is placed on the cornea, the surgeon inserts the second corneal marker into the vacuum guide and presses it against the patients cornea to form radial marks on the cornea to guide surgery.

A suitable corneal marker is illustrated in Figures 26A-26B. Figure 26A is a side view and Figure 26B is an end view of corneal marker (700). This corneal marker has a housing (710) to which incision markers, radial pocket markers, channel or pocket markers, and a positioner may be attached as desired. The incision marker and radial pocket markers are inked with a dye prior to aligning